

Treatment Interventions in Nursing Home Residents With Urinary Incontinence: A Systematic Review of Randomized Trials

HOWARD A. FINK, MD, MPH; BRENT C. TAYLOR, PhD; JIM W. TACKLIND, BS; INDULIS R. RUTKS, BS;
AND TIMOTHY J. WILT, MD, MPH

OBJECTIVE: To determine the efficacy and safety of treatments for nursing home residents with urinary incontinence (UI).

PATIENTS AND METHODS: A systematic review was conducted of randomized controlled trials published from January 1985 through May 2008. Data sources were MEDLINE and Cochrane Library databases, proceedings of the 3rd International Consultation on Incontinence, and reference lists of retrieved clinical trials and review articles. Trials were eligible if they consisted of nursing home or long-term institutionalized residents with UI. Eligible trials compared interventions for improving UI with controls, including comparisons of UI outcomes and/or adverse events between randomized groups.

RESULTS: Fourteen unique clinical trials, consisting of 1161 patients, met inclusion criteria. Treatments included antimuscarinic medications, oral estrogen plus progesterone, and behavioral interventions (eg, prompted voiding). Compared with usual care, prompted voiding alone or prompted voiding plus exercise reduced daytime incontinence and increased appropriate toileting. Efficacy outcomes indicated that neither prompted voiding plus exercise nor prompted voiding plus oral estrogen and progesterone was superior to prompted voiding alone for incontinence management. Prompted voiding plus oxybutynin slightly reduced incontinence compared with prompted voiding plus placebo.

CONCLUSION: In nursing home residents with UI, prompted voiding alone and prompted voiding with exercise were associated with modest short-term improvement in daytime UI. Results do not clearly support an independent effect of exercise in improving UI. Oxybutynin may provide small additional benefit when used with prompted voiding. There appears to be no role for oral estrogen in UI treatment. Long-term clinical trials of prompted voiding alone, prompted voiding with exercise, and antimuscarinic medications should be conducted with targeted nursing home residents who have UI. These trials should include measures of UI, patient quality of life, and cost outcomes.

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FIT = functional incidental training; MMSE = Mini-Mental State Examination; UI = urinary incontinence

Urinary incontinence (UI) affects more than half of nursing home residents in the United States,¹⁻³ leading to such health consequences as pressure ulcers,^{4,5} urinary tract infections,⁶ falls,⁷ worsened quality of life,⁸ and caregiver morbidity including stress and depressed mood.^{9,10} Incremental costs of caring for nursing home residents with UI or fecal incontinence, including costs of labor, laundry, and supplies, have been estimated at nearly \$10,000 per patient annually.^{11,12}

Although not demonstrated in randomized controlled trials to improve UI symptoms,¹³ clinical guidelines recommend¹⁴ and the US Department of Health and Human Ser-

vices' Centers for Medicare and Medicaid Services mandate¹⁵ that modifiable risk factors for UI be identified and corrected in all patients with UI. The Centers for Medicare and Medicaid Services further mandates that each nursing home resident who has UI be provided with "appropriate treatment and services to achieve or maintain as much normal urinary function as possible," thereby establishing a high priority for treatments aimed at improvements in UI, such as behavioral interventions, medications, and/or surgery.¹⁶⁻¹⁸ By comparison, the use of incontinence pads and briefs and catheterization are considered lower priority—alternative-management approaches aimed not at improvements in UI but at urine containment.

Data suggest that behavioral interventions (eg, prompted voiding, habit retraining, timed voiding) are used for approximately 20% to 40% of nursing home residents with UI.^{16,17} Prompted voiding involves caregivers querying and checking residents for wetness, providing toileting prompts, and offering positive feedback for dryness and/or appropriate toileting requests.¹⁹ Habit retraining involves development of an individualized toileting schedule to preempt involuntary bladder emptying while maximizing continent voiding intervals.²⁰ Timed voiding involves bringing the resident to toilet at fixed intervals, regardless of whether he or she requests it or has voided during the most recent prior interval.²¹

Medications, primarily antimuscarinic agents, are widely used for community-dwelling patients who have overactive bladder or UI, but these drugs appear to be used

From the Geriatric Research Education and Clinical Center (H.A.F.) and Center for Chronic Disease Outcomes Research and Veterans Affairs Coordinating Center of the Cochrane Review Group in Prostate Diseases and Urologic Malignancies (H.A.F., B.C.T., J.W.T., I.R.R., T.J.W.), Veterans Affairs Medical Center, Minneapolis, MN; and Department of Medicine University of Minnesota, Minneapolis (H.A.F., T.J.W.).

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Individual reprints of this article are not available. Address correspondence to Howard A. Fink, MD, MPH, VA Medical Center, 1 Veterans Dr, Box 11G, Minneapolis, MN 55417 (howard.fink@va.gov).

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for relatively few nursing home residents who have UI.¹⁷ Although antimuscarinic agents may improve urge UI, they are associated with certain adverse effects to which elderly nursing home residents may be prone, including dry mouth, urinary retention, constipation, and cognitive impairment.^{22,23} Consequently, the balance of benefits and risks may differ between nursing home residents and other patients with UI.

Given the large and growing burden of UI among nursing home residents, we conducted this systematic review of randomized controlled trials to more precisely estimate the magnitude of benefits and adverse effects associated with specific UI treatments within this population.

PATIENTS AND METHODS

LITERATURE SEARCH

We searched the US National Library of Medicine's MEDLINE database for English-language literature published from January 1985 through May 2008, using the following key terms: *(long-term care OR nursing homes OR nursing hom\$.mp) AND (urinary incontinence OR incontinence OR urin\$ adj3 incont\$.tw) AND (clinical trial, phase III OR clinical trial, phase IV OR controlled clinical trial OR meta-analysis OR randomized controlled trial OR review)*. We searched the Cochrane Library's Cochrane Central Register of Controlled Trials database for English-language literature published from January 1985 through May 2008, using the following terms: *[(urinary AND incontinence) OR (urin* AND incont*)] AND [(long-term care OR nursing home OR (nurs* AND hom*)]*. The Cochrane search also captured Elsevier Publishing's EMBASE database because the UK Cochrane Centre annually searches EMBASE for randomized controlled trials and adds them to the Cochrane Library. The most recent EMBASE search was completed through 2006.²⁴

In addition, we examined the proceedings of the 3rd International Consultation on Incontinence²⁵ and the references lists of retrieved clinical trials and review articles for information on further trials.

SELECTION CRITERIA

All eligible trials had to meet the following criteria: (1) consist of nursing home or long-term institutionalized residents with UI; (2) be randomized, with comparisons of interventions aimed at improvements in UI with placebo or active control; (3) compare relevant UI outcomes and/or adverse events between randomized groups; and (4) be published in the English language.

Two reviewers (H.A.F. and J.W.T. or I.R.R.) independently assessed study eligibility. Differences in eligibility assessments were resolved by discussion between these reviewers.

OUTCOME MEASURES

Two reviewers (H.A.F. and J.W.T. or I.R.R.) independently extracted information on trial characteristics, patient demographics, inclusion/exclusion criteria, patient withdrawals, treatment efficacy, and adverse events in a standardized manner. Measures of trial efficacy outcomes considered for inclusion in the current review included the following: patient- or provider-reported UI presence/severity, percentage of patient examinations detecting incontinence of urine, proportion of toileting attempts that were continent, and validated UI symptom scores.

ASSESSMENT OF METHODOLOGIC QUALITY

We assessed each trial's quality of concealment of randomized treatment allocation, assigning scores ranging from 1 (poorest quality) to 3 (best quality).²⁶ In addition, we assessed whether trial participants and investigators were blinded to treatments provided, whether trials used intention-to-treat analyses, and whether numbers of participants and reasons for study withdrawals were adequately described for each treatment group.

STATISTICAL ANALYSES

Because of the heterogeneity in treatment interventions and efficacy outcome measures used in included trials, results for individual trials were analyzed and are presented in the current review without statistical pooling.

RESULTS

STUDY SELECTION

The flow of selection of randomized controlled trials of nursing home residents with UI is presented in the Figure. The MEDLINE and Cochrane Library literature searches led to identification of 171 and 90 potentially eligible articles, respectively. Investigators initially agreed on eligibility for 163 articles (95%) identified from MEDLINE ($\kappa=0.91$) and 79 articles (88%) identified from the Cochrane Library ($\kappa=0.76$). After final consensus was reached through discussion, 15 articles identified from MEDLINE and 16 articles from the Cochrane Library met all inclusion criteria. Eight articles identified from the proceedings of the 3rd International Consultation on Incontinence met all inclusion criteria.

Collectively, the 3 sources yielded 20 reports of 14 unique trials that met inclusion criteria, with 6 articles being duplicate reports. No additional eligible trials were identified from the reference lists of retrieved trials and review articles.

CHARACTERISTICS OF TRIALS

Table 1 shows the characteristics of the 14 randomized controlled trials of nursing home patients with UI. The 8

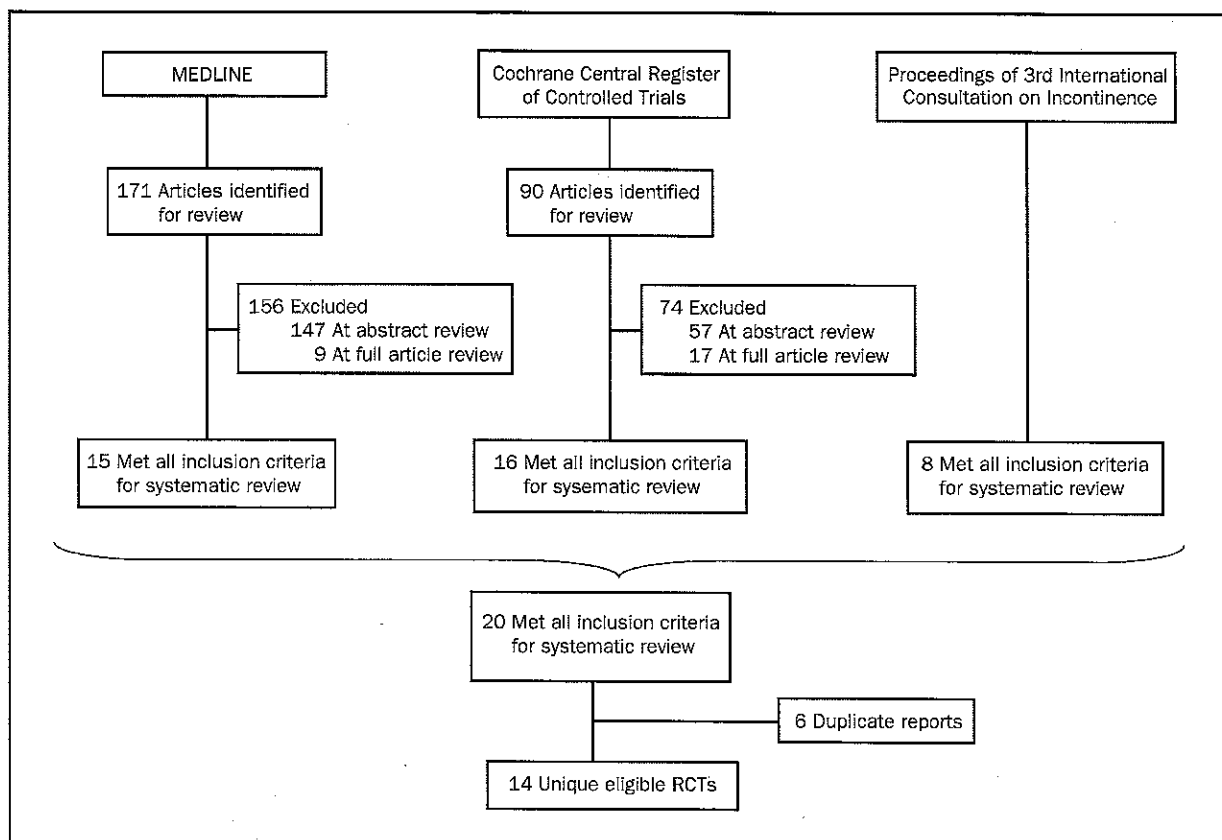


FIGURE. Flow diagram showing identification and selection of randomized controlled trials (RCTs) of nursing home residents with urinary incontinence. Most articles were identified from more than 1 source. Collectively, from MEDLINE, Cochrane Library's Cochrane Central Register of Controlled Trials, and the proceedings of the 3rd International Consultation on Incontinence, 20 articles were identified.

trials of behavioral interventions and 6 trials of pharmacological interventions consisted of a total of 1161 participants, with individual trial sample sizes ranging from 12 to 190.²⁷⁻⁴⁰ Six duplicate reports⁴¹⁻⁴⁶ were evaluated for additional methods and outcomes data that were not provided in the initial reports. Ten trials used a parallel treatment group design,^{28-31,33-36,39,40} whereas 4 trials used a crossover design.^{27,32,37,38} Treatment duration of the trials ranged from 4 days to 32 weeks. One trial included results of a final follow-up assessment from 22 weeks after end of treatment.²⁸

With respect to quality assessments of included trials (Table 2), all trials were reported as being randomized, although only 5 trials included descriptions of adequate methods of random allocation and concealment of treatment assignment.^{30,32,33,38,40} Four trials were reported to be double-blind,^{32,36,37,40} 3 trials had outcome assessors who were masked to treatment allocation,^{30,38,39} 1 trial had masked patients and clinical staff but unmasked outcome assessors,²⁷ and 1 trial had outcome assessors masked to treatment group for most participants.³⁸ Only 2 trials appeared

to include all randomized participants in their outcomes analyses.^{35,40}

Trials consisted of evaluations of behavioral interventions (eg, prompted voiding),^{28-31,34,35,38,39} antimuscarinic medications,^{27,32,37,40} and prompted voiding in combination with oral estrogen and progesterone.³³ Common inclusion criteria were patient age 60 to 65 years^{27-29,33,34,37-40} and ability of patient to pass a basic cognitive test (eg, recognizing own name, Folstein Mini-Mental State Examination [MMSE] score above a specified threshold).^{28-34,38-40} Several trials excluded patients who had indwelling urinary catheters,^{30-32,35,39,40} and 5 trials excluded patients with paralysis or severe physical immobility.^{31,33,38-40}

In most trials, efficacy outcomes were based on research staff examinations of study participants for signs of UI (ie, wet checks) and prompts to void every hour^{28,29,34} or every 2 hours.^{27,30-32,35,37,38} Wet checks were restricted to daytime in all but 4 trials.^{27,34,35,37} The most commonly used outcome measures were the percentage of wet checks showing incontinence of urine and the appropriate toileting

TABLE 2. Quality Assessment of Randomized Controlled Trials of Nursing Home Patients With Urinary Incontinence

| Reference | Adequacy of randomization concealment | Blinding | Intention-to-treat analysis | Withdrawals adequately described |
|--------------------------------------|---------------------------------------|---|-----------------------------|----------------------------------|
| Behavioral interventions | | | | |
| Schnelle et al, ²⁹ 1989 | Uncertain | Not stated | No | Yes |
| Hu et al, ²⁸ 1989 | Uncertain | Not stated | No | Yes |
| Surdy, ³⁵ 1992 | Uncertain | No | Yes | No withdrawals |
| Colling et al, ³⁴ 1992 | Quasirandomized | Not stated | No | Yes |
| Schnelle et al, ³¹ 1995 | Uncertain | No ^a | No | Yes |
| Schnelle et al, ³⁰ 2002 | Adequate | Outcomes assessors only | No | Yes ^b |
| Ouslander et al, ³⁸ 2005 | Adequate | Outcomes assessors only ^c | No | No ^d |
| van Houten et al, ³⁹ 2007 | Uncertain | Outcomes assessors only | No | Yes |
| Pharmacological interventions | | | | |
| Zorzitto et al, ²⁷ 1985 | Uncertain | Patients and clinical staff, but not outcomes assessors | No | No |
| Hall, et al et al ³⁶ 1987 | Uncertain | Yes ^e | No | Yes |
| Zorzitto et al, ³⁷ 1989 | Uncertain | Yes ^e | No | Yes |
| Ouslander et al, ³² 1995 | Adequate | Yes ^e | No | Yes |
| Ouslander et al, ³³ 2001 | Adequate | Not stated ^f | No | Yes |
| Lackner et al, ⁴⁰ 2008 | Adequate | Yes ^e | Yes | Yes |

^a Only "approximately 10%" of assessments were blinded to treatment assignment.

^b Reason for withdrawal reported for 38 of 42 participants.

^c Outcome assessor was masked to treatment assignment for most participants; treatment assignment became apparent in a small number of participants during the study.

^d Reason for withdrawal reported for two-thirds of participants.

^e Reported as "double-blinded."

^f Assessment blinded for vaginal atrophy and inflammation measures, but blinding not specified for urinary incontinence outcomes.

ratio, with the latter defined as the proportion of voids (continent and incontinent) for which the participant used a toilet or toilet substitute (eg, commode).

DEMOGRAPHICS OF PATIENTS

The characteristics of study patients, such as age, sex, mean MMSE score, and ambulatory ability, are included in Table 1. Most patients were elderly women, with a mean age of 74 years or older. Few trials reported data on participant race and/or comorbidity.

Study participants generally had moderate to severe cognitive impairment and limited ability to ambulate or independently perform activities of daily living.

EFFICACY OUTCOMES

The efficacy outcomes of the trials, divided into those that used behavioral interventions and those that used pharmacological interventions, are presented in Table 3.

Behavioral Interventions. Five trials compared the efficacy of a toileting behavioral intervention with that of usual care for nursing home residents with UI, consistently showing greater improvement in continence with behavioral intervention.^{28,29,34,35,39}

Schnelle et al²⁹ compared daytime prompted voiding with usual care during 5-day to 10-day periods. Prompted voiding reduced the percentage of incontinent wet checks compared with usual care (18% vs 35%, respectively; $P < .001$) and increased the appropriate toileting ratio (59%

vs 17%; $P < .001$). Hu et al²⁸ reported that patients who were randomized to receive daytime prompted voiding had a mean of 0.57 fewer incontinent wet checks per day at 13 weeks after treatment initiation than at baseline ($P < .05$), whereas no significant improvement was observed in patients receiving usual care (0.17 fewer incontinent wet checks per day at 13 weeks vs baseline; $P \geq .05$). For patients in whom data were available at 22 weeks after treatment end, those in the prompted voiding group had a mean of 0.5 fewer incontinent wet checks than at baseline (P value not reported), a finding the authors attributed to patients' increased self-initiated toileting requests.²⁸

Colling et al³⁴ compared usual care with an intervention in which an individualized toileting prescription was developed for each nursing home resident on the basis of an analysis of his or her 24-hour voiding pattern. Residents in the active treatment group had a significant decline from baseline in the proportion of incontinent voids per day (average of 0.57 throughout the entire treatment period vs 0.7 at baseline; $P < .001$). Residents in the active treatment group also had fewer incontinent wet checks per day after 12 weeks of treatment than at baseline (3.9 vs 4.8, respectively; P value not reported). In the usual care group, there was no reported change in incontinence frequency from baseline.³⁴

In a study of male veterans, Surdy³⁵ reported that 24-hour prompted voiding resulted in a reduced rate of incontinent wet checks after 7 weeks of treatment compared with

TABLE 3. Efficacy Outcomes of Randomized Controlled Trials of Nursing Home Patients With Urinary Incontinence^a

| Reference | Treatment group (No. of patients) | Incontinent wet checks ^b | Appropriate toileting ratio ^c |
|--|--|--|---|
| Behavioral interventions | | | |
| Schnelle et al, ²⁹ 1989 | Usual care (63) | 34.5% | 16.8% |
| | PV (63) | 17.8% ($P<.001$) | 59.4% ($P<.001$) |
| Hu et al, ²⁸ 1989 | Usual care (68) | 0.17 fewer UI episodes per day vs baseline ($P\geq.05$) | NR |
| | PV (65) | 0.57 fewer UI episodes per day vs baseline ($P<.05$) | NR |
| Surdy, ³⁵ 1992 | Usual care (6) | 45.9% | NR |
| | PV (6) | 13.2% ($P<.001$) | 68.7% ($P=.01$ within group) |
| Colling et al, ³⁴ 1992 | Usual care (37) | 4.8 per day (no change from baseline) | NR |
| | Patterned urge-response toileting (51) | 3.9 per day | NR |
| Schnelle et al, ³¹ 1995 | PV (40) | No numerical data provided. "Both [groups] showed large and similar decreases in incontinence frequencies from baseline." | |
| Schnelle et al, ³⁰ 2002 | Usual care (74) | 35% | 16% |
| | PV + FIT (73) | 23% ($P<.01$) | 59% ($P<.01$) |
| Ouslander et al, ³⁸ 2005 | Usual care (43) | Median of 50% vs 41% at baseline | Median of 0% vs 0% at baseline |
| | PV + FIT (35) | Median of 25% vs 54% at baseline ($P<.001$) | Median of 54% vs 0% at baseline ($P<.001$) |
| van Houten et al, ³⁹ 2007 | Usual care (28) | Compared with active intervention, 41% improved in toilet timing test during daytime, 33% during nighttime ($P=.05$; $P=.06$); 7% changed from dependent to independent toileting, 11% from independent to dependent toileting ($P=.14$; $P=.70$) | |
| | Individualized mobility and toileting skill training (29) | Compared with usual care, intervention group had 8% less involuntary urine loss ($P=.07$); 65% improved in toilet timing test during daytime, 58% during nighttime; 21% changed from dependent to independent toileting, 14% from independent to dependent toileting | |
| Pharmacological interventions | | | |
| Zoritto et al, ²⁷ 1986 ^d | Placebo, 15 mg 4 times daily ^e | 34% | NR |
| | Propantheline, 15 mg 4 times daily ^e | 34% | NR |
| | Placebo, 30 mg 4 times daily ^e | 36% | NR |
| | Propantheline, 30 mg 4 times daily ^e | 30% ($P<.05$) | NR |
| Hall et al, ³⁶ 1987 | Placebo (26) | -0.05 Change in median weekly UI episodes from week 7-26 ($P=.29$) | NR |
| | Procaine-hematoporphyrin, 100 mg once daily (30) | -2.13 Change in median weekly UI episodes from week 7-26 | NR |
| Zoritto et al, ³⁷ 1989 ^d | Placebo (18) | 25% | NR |
| | Oxybutynin IR, 5 mg twice daily (18) | 27% ($P=.57$) | NR |
| Ouslander et al, ³³ 1995 | PV + placebo (63) | 7.7 per 72 h (23.7%) | 41.9% |
| | PV + oxybutynin IR, 2.5-5 mg 3 times daily (63) | 6.6 per 72 h (20.2%) ($P=.01$) | 47.8% |
| Ouslander et al, ³³ 2001 | PV + placebo (16 at 3 mo, 12 at 6 mo) | 26% at 3 mo, 32% at 6 mo | NR |
| | PV + oral estrogen, 0.625 mg once daily + progesterone, 2.5 mg once daily (13 at 3 mo, 9 at 6 mo) | 24% at 3 mo, 28% at 6 mo ("no significant difference") | NR |
| Lackner et al, ⁴⁰ 2008 | Placebo (24) ^f | NR | NR |
| | Oxybutynin ER, 5 mg once daily (26) ^f | NR | NR |

^a ER = extended release; FIT = functional incidental training (prompted voiding [PV] plus individualized endurance and strengthening exercise); IR = immediate release; NR = not reported; UI = urinary incontinence.

^b Wet check results were variously reported as mean percentage of all incontinent wet checks, mean number of incontinent wet checks per period, or mean or median change in percentage of incontinent wet checks.

^c Appropriate toileting ratio was defined as the proportion of total voids (continent and incontinent) for which the participant used a toilet or toilet substitute.

^d Because some patients were checked for continence multiple times within a 2-hour interval, the trial reported results for the percentage of 2-hour intervals that were continent rather than the percentage of wet checks that were continent.

^e In this crossover trial, 43 participants were randomized to phase 1 (placebo vs propantheline, 15 mg 4 times daily), 34 participants completed phase 1, 30 participants were randomized to phase 2 (placebo vs propantheline, 30 mg 4 times daily), and 24 participants completed phase 2.

^f Number refers to participants with adverse events data; trial did not report any urinary incontinence outcomes data.

usual care (13% vs 46%, respectively; $P<.001$). In addition, the appropriate toileting ratio with treatment in the

prompted voiding group (69%) was significantly improved compared with baseline ($P=.01$). van Houten et al³⁹ com-

pared interventions of individualized mobility and toileting skill training vs usual care for a period of 8 weeks in nursing home residents. Compared with residents randomized to receive usual care, those allocated to receive active intervention had 8% less involuntary urine loss, as measured by diaper weight ($P=.07$). In addition, residents receiving active intervention were more likely to show improvements in the toilet timing test compared with residents receiving usual care (proportion with daytime improvement, 65% vs 41%, respectively; $P=.05$; proportion with nighttime improvement, 58% vs 33%; $P=.06$). However, nursing home residents receiving active intervention were not significantly more likely than residents receiving usual care to change from dependent to independent toileting.³⁹

Three clinical trials reported results of functional incidental training (FIT), in which individualized, graded strength and endurance exercises are integrated into a daytime prompted voiding routine.^{30,31,38} In these trials, nursing home residents allocated to receive FIT showed greater improvement in UI than did residents who received usual care, although there was not clear evidence of benefit from FIT vs prompted voiding alone.

In 1995, Schnelle et al³¹ compared 8 weeks of prompted voiding vs FIT. The authors reported no numerical UI results, stating only that large, similar decreases in UI frequencies were seen in both the prompted voiding group and the FIT group compared with baseline. In 2002, Schnelle et al³⁰ compared 32 weeks of FIT vs usual care; they found that the FIT group had a reduced rate of incontinent wet checks compared with usual care (23% vs 35%, respectively; $P<.01$) and an increased appropriate toileting ratio (59% vs 16%; $P<.01$).

In a crossover design study, Ouslander et al³⁸ compared 8 weeks of FIT with usual care. Participants receiving FIT showed greater improvement in incontinent wet checks than did participants receiving usual care. The median percentage of incontinent wet checks in the FIT group decreased from 54% at baseline to 25% at 8 weeks, whereas this percentage in the usual care group increased from 41% at baseline to 50% at 8 weeks ($P<.001$). The median appropriate toileting ratio increased from 0% at baseline to 54% at 8 weeks in the FIT group compared with 0% at both baseline and 8-week follow-up in the usual care group ($P<.001$).³⁸

Pharmacological Interventions. Pharmacological interventions resulted in small and inconsistent effects in nursing home residents with UI. Four trials evaluated the efficacy of antimuscarinic medications.^{27,32,37,40}

Zorzitto et al²⁷ conducted a crossover study of patients who had urodynamically demonstrated detrusor instability and a postvoid residual urine volume of less than 50 mL. In

phase 1 of the trial, participants were randomized to receive propantheline (15 mg 4 times daily) or placebo for a period of 4 days, with a 3-day washout before crossover. In phase 2, participants were randomized to receive a higher dose of propantheline (30 mg 4 times daily) or placebo for an additional 4 days, again with a 3-day washout. The percentage of incontinent 2-hour intervals did not differ between groups in phase 1 (34% for both the low-dose propantheline and the placebo groups; $P>.05$). However, in phase 2 the high-dose propantheline group had marginally reduced incontinent intervals compared with the placebo group (30% vs 36%, respectively; $P<.05$).²⁷

Ouslander et al³² conducted a crossover study of patients who had urodynamically defined detrusor instability or a clinical history consistent with urge UI and a bladder capacity of less than 300 mL (as demonstrated by cystometry). All patients were receiving, although none had responded to, prompted voiding. In the crossover study, the patients continued receiving prompted voiding and were randomized to also receive 20 days of immediate-release oxybutynin chloride (2.5-5 mg 3 times daily) or placebo, with a 3-day to 5-day washout before crossover. The oxybutynin group, compared with the placebo group, had a reduced rate of incontinent wet checks (20% vs 24%, respectively; $P=.01$) and a possibly higher appropriate toileting ratio (48% vs 42%; P value not reported).³²

Zorzitto et al³⁷ reported results of a crossover study of patients who had urodynamically defined detrusor instability and a postvoid residual urine volume of less than 50 mL. Patients were randomized to receive 8 days of immediate-release oxybutynin (5 mg twice daily) or placebo, with a 6-day washout before crossover. The trial found no significant difference between the oxybutynin and placebo groups in the percentage of continent 2-hour intervals (27% vs 25%, respectively; $P=.57$).³⁷ Lackner et al⁴⁰ evaluated women with symptomatically defined UI who were randomized to receive 4 weeks of extended-release oxybutynin (5 mg/d) or placebo. However, these authors reported no UI outcomes.

Hall et al³⁶ studied patients with urge incontinence attributed to neurogenic bladder, comparing the use of procaine hematoporphyrin (100 mg/d) with placebo. The change in median incontinent episodes per week, from week 7 to week 26 of the trial, was -2.13 and -0.05 for the procaine and placebo groups, respectively ($P=.29$ for between-group comparison).

A 6-month trial by Ouslander et al³³ consisted of older women who predominantly had urge UI or functional UI. Compared with women who received prompted voiding plus daily placebo, women who received prompted voiding plus oral estrogen (0.625 mg/d) and progesterone (2.5 mg/d) did not have a significantly lower percentage of

incontinent wet checks (26% vs 24%, respectively, at 3 months; 32% vs 28%, respectively, at 6 months). No *P* values were reported, but the authors described these differences as "not significant."

ADVERSE EVENTS

Adverse events and patient withdrawals are presented in Table 4.

Patient Withdrawals. The patient withdrawal rate in the trials ranged from 0% to 40%, with most withdrawals attributed to acute illness, hospitalization, death, or transfer to another facility. Withdrawals attributed to adverse effects included no cases in the oral estrogen trial,³³ 1.5% of cases in the procaine trial (1 patient in placebo group with rash),³⁶ and 12% of cases in the propantheline trial (4 patients in propantheline group with ileus, nausea and vomiting, urinary retention, syncope; 1 patient in placebo group).²⁷

In the 2 immediate-release oxybutynin trials, withdrawals attributed to adverse effects occurred at rates of 5% (2 patients with urinary retention, 2 patients with allergy; treatment groups not specified)³² and 17% (1 patient in oxybutynin group with dry mouth, 2 patients in placebo group with lethargy and nausea, 1 patient during washout with shortness of breath).³⁷ In the 4-week trial of extended-release oxybutynin,⁴⁰ withdrawals attributed to adverse effects occurred at rates of 4% in the oxybutynin group and 0% in the placebo group (1 patient with excessive postvoid residual urine volume).

Adverse Effects. In the oral estrogen trial,³³ 2 patients (13%) using the active drug had single episodes of vaginal spotting, and "about 10%" of patients (treatment group not specified) experienced mild breast discomfort. In the procaine trial,³⁶ the authors reported that "no adverse reactions attributable to [procaine] were seen." In the propantheline trial,²⁷ adverse effects in phase 1 (propantheline, 15 mg 4 times daily vs placebo) included dry mouth (26% for propantheline vs 12% for placebo), constipation (12% vs 9%), and miscellaneous (eg, decreased appetite, syncope, drowsiness, depression, somnolence, lethargy; 23% vs 7%).

In both immediate-release oxybutynin trials,^{32,37} the most commonly reported adverse effect was dry mouth. In the larger trial,³² which reported more detailed data on adverse effects, the frequency of adverse effects in patients in the oxybutynin and placebo groups, respectively, were as follows: dry mouth, 42% vs 35%; incomplete bladder emptying, 25% vs 31%; constipation, 30% vs 25%; urinary hesitancy, 15% vs 13%; urinary straining, 13% vs 18%; insomnia, 22% vs 15%; headache, 20% vs 11%; and reflux/heartburn, 9% vs 20%. In the 4-week extended-release oxybutynin trial,⁴⁰ no differences were reported between

the oxybutynin and placebo groups in any cognitive measure, including the MMSE, Confusion Assessment Method, Severe Impairment Battery, and Brief Agitation Rating Scale. The most common adverse effects in the oxybutynin and placebo groups, respectively, were cough (12% vs 13%), constipation (8% vs 0%), falls (4% vs 8%), and dry mouth (4% vs 4%), with no significant differences between groups.⁴⁰

In the behavioral intervention trials, one trial³⁸ reported no adverse effects, such as falls, muscle strains, or bruises, among patients receiving prompted voiding and FIT. No other behavioral studies reported data for adverse effects.

DISCUSSION

The treatment trials of nursing home residents with UI were generally small in sample size, short in duration, and, in some cases, methodologically weak. The trials included relatively few men and provided limited data regarding the efficacy and adverse effects of pharmacological treatments.

Regarding the intervention of prompted voiding, the results presented in the current review are consistent with those reported in a previous systematic review,¹⁹ despite the addition of newer trials. In nursing home populations with substantial cognitive and mobility limitations, prompted voiding alone, compared with usual care, was associated with small improvements in UI episodes and appropriate toileting behavior for as long as 3 months of treatment. Partial benefit of prompted voiding was possibly sustained for several months after treatment.²⁸ Most evidence supports the efficacy of prompted voiding in reducing daytime UI.

Results of the current review neither support nor provide clear evidence against the benefit of exercise in the treatment of nursing home residents with UI. Results of 2 trials showed that FIT, a program of strength and endurance exercises combined with prompted voiding, significantly reduced UI episodes and improved appropriate toileting behavior compared with usual care.^{30,38} However, a separate trial found that FIT provided no greater benefit for UI outcomes than did prompted voiding alone.³¹

Despite clinical trial evidence indicating that prompted voiding alone and prompted voiding plus exercise are modestly effective in improving daytime UI, at least for the short term, implementation of these costly, labor-intensive interventions into clinical practice has been limited.⁸ Compared with routine toileting care, labor costs for treatment of patients with UI have been estimated to be 300% greater for FIT and 25% greater for prompted voiding.⁴⁴ Even when accounting for potential savings in laundry and supply costs, prompted voiding has been estimated to save

TABLE 4. Adverse Events in Randomized Controlled Trials of Nursing Home Patients With Urinary Incontinence^a

| Reference | Treatment group | Withdrawals, % (No./No. of patients) | Withdrawals because of AEs, % (No./No. of patients) | AEs, % |
|--------------------------------------|---|--|--|--|
| Behavioral interventions | | | | |
| Schnelle et al, ²⁹ 1989 | Usual care | 19.2 (30/156) ^b | NR | NR |
| | PV | | | |
| Hu et al, ²⁸ 1989 | Usual care | 4.2 (3/71) | NR | NR |
| | PV | 9.7 (7/72) | | |
| Surdy, ³⁵ 1992 | Usual care | 0 (0/6) | 0 | NR |
| | PV | 0 (0/6) | 0 | |
| Colling et al, ³⁴ 1992 | Usual care | 26.0 (13/50) | NR | NR |
| | Patterned urge-response toileting | 19.0 (12/63) | | |
| Schnelle et al, ³¹ 1995 | PV | 19.1 (18/94) ^b | NR | NR |
| | PV + FIT | | | |
| Schnelle et al, ³⁰ 2002 | Usual care | 22.9 (22/96) | NR | NR |
| | PV + FIT | 21.3 (20/94) | | |
| Ouslander et al, ³⁸ 2005 | Usual care | 21.8 (12/55) ^c | NR | NR |
| | PV + FIT | 32.7 (17/52) | 0 | 0 |
| van Houten et al, ³⁹ 2007 | Usual care | 3.6 (1/28) | NR | NR |
| | Individualized mobility and toileting skill training | 10.3 (3/29) | | |
| Pharmacological interventions | | | | |
| Zorzitto et al, ²⁷ 1986 | Placebo, 15 mg 4 times daily | 20.9 (9/43) ^b | 9.3 (4/43), active drug; 2.3 (1/43), placebo | Dry mouth, 12; constipation, 9; miscellaneous, 7 |
| | Propantheline, 15 mg 4 times daily | | | Dry mouth, 26; constipation, 12; miscellaneous, 23 |
| | Placebo, 30 mg 4 times daily | 20.0 (6/30) ^d | | |
| | Propantheline, 30 mg 4 times daily | | | |
| Hall et al, ³⁶ 1987 | Placebo | 18.8 (6/32) | 3.1 (1/32) | NR |
| | Procaine-hematoporphyrin, 100 mg once daily | 9.1 (3/33) | 0 (0/33) | 0 |
| Zorzitto et al, ³⁷ 1989 | Placebo | 25.0 (6/24) ^b | n=2 ^e | Dry mouth, 33; constipation, 8; nausea, 8; vomiting, 8; lethargy, 4; confusion, 8 |
| | Oxybutynin IR, 5 mg twice daily | | n=1 ^e | Dry mouth, 29; constipation, 13; nausea, 0; vomiting, 0; lethargy, 8; confusion, 0 |
| Ouslander et al, ³² 1995 | PV + placebo | 16.0 (12/75) ^b | 5.3 (4/75) ^e | Dry mouth, 35; incomplete bladder emptying, 31; constipation, 25; reflux/heartburn, 20; insomnia, 15 |
| | PV + oxybutynin IR, 2.5-5 mg 3 times daily | | | Dry mouth, 42; incomplete bladder emptying, 25; constipation, 30; reflux/heartburn, 9; insomnia, 22 |
| Ouslander et al, ³³ 2001 | PV + placebo | 29.4 (5/17) | 0 | Mild breast discomfort, "about 10%" |
| | PV + oral estrogen, 0.625 mg once daily + progesterone, 2.5 mg once daily | 40.0 (6/15) | 0 | Vaginal spotting, 13; mild breast discomfort, "about 10%" |
| Lackner et al, ⁴⁰ 2008 | Placebo | 8.3 (2/24) | 0 | Cough, 13; constipation, 0; falls, 8; dry mouth, 4 |
| | Oxybutynin ER, 5 mg once daily | 3.8 (1/26) | 3.8 (1/26) | Cough, 12; constipation, 8; falls, 4; dry mouth, 4 |

^a AE = adverse effect; ER = extended release; FIT = functional incidental training (prompted voiding [PV] plus individualized endurance and strengthening exercise); IR = immediate release; NR = not reported.

^b No withdrawal data were provided separately for treatment groups.

^c Withdrawal results are for phase 1 of the crossover; 72.9% of randomized participants (78/107) completed phase 1; 78.2% (61/78) completed phase 2.

^d Only the 30 patients who completed phase 1 (crossover of placebo and propantheline) and the washout phase were randomized to phase 2. No withdrawal data were provided separately for treatment groups in phase 2.

^e One additional participant withdrew because of shortness of breath during washout period. The percentage of withdrawals because of AEs could not be determined by treatment arm because this crossover study did not report the number of participants in each treatment arm. Overall, 4 (16.7%) of 24 participants enrolled in the study withdrew because of AEs.

overall costs of nursing home patient care only when its benefit was assumed to persist considerably longer than has been shown in trials⁴¹ or when a prompted voiding group was compared with a control group receiving frequent (ie, hourly) checking and changing for incontinence.⁴⁷ Some authors have suggested that staffing requirements for implementation of an incontinence and exercise intervention may exceed resources currently available in most nursing homes³⁰ and that turnover rates and attitudes toward care among nursing home staff are additional implementation barriers to effective prompted voiding-based interventions.²⁵

No trials of timed voiding were included in the current review because no such trials located in the literature search appeared to be randomized. A previous systematic review²¹ reported on 2 studies that each compared usual care with timed voiding in combination with additional interventions. The authors of that earlier review concluded that data were too few and of insufficient quality to provide support for or against timed voiding for treatment of nursing home patients with UI.

Trial results for the use of oxybutynin in nursing home patients with UI and urodynamically defined detrusor instability appeared to be mixed. In addition, trials showed no clear benefit for the use of propantheline²⁷ or procaine-hematoporphyrin³⁶ in these patients. Adverse effects, such as dry mouth, urinary retention, constipation, and insomnia, were common with the use of antimuscarinic agents.

Recent systematic reviews that examined the efficacy and adverse effects of antimuscarinic medications for management of overactive bladder symptoms in noninstitutionalized adult patient populations^{22,48-52} concluded that these medications were more effective than placebo⁴⁸⁻⁵¹ or nonpharmacological active therapies.⁵² However, results of the studies differed regarding whether these benefits were clinically meaningful.^{49,50} As a drug class, antimuscarinic agents more often caused dry mouth than did placebo, but risks of adverse effects and of treatment discontinuation because of adverse effects appeared to differ between specific drugs and formulations.

Several trials of antimuscarinic agents have been conducted with community-dwelling individuals consisting entirely⁵³ or predominantly⁵⁴ of older patients with UI. Some trials of antimuscarinic agents have included stratified analyses of older patients with UI.⁵⁵ These trials reported that treatment with immediate-release oxybutynin, immediate-release tolterodine tartrate, and extended-release tolterodine tartrate improved patients' urinary symptoms more than did placebo.

The applicability of these results to the nursing home population with UI is uncertain. Although potential adverse effects associated with antimuscarinic agents, including

dry mouth, urinary retention, constipation, and cognitive impairment, may be more problematic in frail nursing home residents, a recent 4-week trial consisting of a small group of selected nursing home patients with UI appeared to find no significant difference in adverse outcomes between patients randomized to receive extended-release oxybutynin and those randomized to receive placebo.⁴⁰ The balance of benefits and adverse effects of treatment of nursing home residents with UI may differ between specific antimuscarinic agents, as well as between different formulations and doses, although this possibility has not been directly examined.

In a study of older female nursing home residents with urge UI or functional UI, the addition of oral estrogen and progesterone to prompted voiding produced no benefit in improving UI symptoms compared with prompted voiding alone.³³ This lack of benefit from estrogen plus progesterone is supported by results from the National Institutes of Health's Women's Health Initiative, in which approximately 15,000 healthy postmenopausal women with urge, stress, and mixed UI were randomized to receive placebo, oral estrogen, or oral estrogen plus progesterone. At 1 year after treatment initiation, women in both active treatment groups experienced significantly worse UI than did those allocated to the placebo group.⁵⁶ Thus, at present, there does not appear to be a useful role for oral estrogen in treatment of patients with UI.

The current review was limited by the available evidence. First, as previously noted, the reviewed trials were small in sample size and of short duration, and they varied in the outcomes reported. Second, the appropriateness of the most commonly reported outcome measure, wet check percentage, as a surrogate for nursing home resident satisfaction and quality of life is unknown.⁵⁷ Third, relatively few men were included in the trials, and few trials examined the efficacy and safety of antimuscarinic medications in nursing home residents with UI. Fourth, the generalizability of prompted-voiding trial results may be limited because most trials used research staff rather than nursing home staff to implement the interventions. Finally, results may not be applicable outside US trial settings.

CONCLUSION

Evidence from the current systematic review indicates that prompted voiding alone and prompted voiding plus exercise (ie, FIT) are associated with modest short-term improvement in UI among nursing home residents who have at least a minimum level of cognitive function. However, there is no trial evidence for the long-term effectiveness of prompted voiding plus exercise. Because previous studies have indicated that these interventions do not save health

care costs, justification for their clinical implementation may require demonstration of meaningful functional and quality-of-life improvements. While acknowledging the challenges of performing UI treatment trials and measuring quality of life in nursing home residents, future researchers should strive to design large-scale, long-term trials to examine the effect of these interventions on UI symptoms, patient quality of life, family and nursing home staff satisfaction, and comprehensive cost estimates (eg, labor, laundry, supplies, indirect costs).

Limited evidence suggests that antimuscarinic medications may reduce UI episodes among nursing home residents who are not responsive to prompted voiding. Results of several studies of community-dwelling adults with overactive bladder symptoms and UI suggest that antimuscarinic agents improve UI symptoms, but with a potential increase in such adverse effects as dry mouth and cognitive impairment. In comparison, the balance between benefits and adverse effects from antimuscarinic agents among nursing home residents with UI may be less favorable. However, the effects of antimuscarinic agents in the nursing home population may vary depending on patient characteristics, and these effects should be rigorously investigated in well-designed randomized controlled clinical trials.

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